PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P62557PC00	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/000402	International filing date *(day/month/year)* 15.01.2004	Priority date *(day/month/year)* 17.01.2003
International Patent Classification (IPC) or national classification and IPC A61N1/39		
Applicant HEARTSINE TECHNOLOGIES LIMITED et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the opinion
   - ☒ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☒ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17.11.2004	10.02.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Küster, G Telephone No. +49 89 2399-7240

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/000402

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-13 as originally filed

   Claims, Numbers

   1-6 filed with the demand

   Drawings, Sheets

   1/16-16/16 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☒ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☒ the claims, Nos. 7-13
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/000402

Box No. II Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
   ☐ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
   ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

   see separate sheet

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-6: yes on condition
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-6: yes on condition
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-6
	No:	Claims	

2. Citations and explanations (Rule 70.7):

   see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

   and / or

2. Non-written disclosures (Rule 70.9)

   see separate sheet

Re Item II
Priority

The priority date appears to be validly claimed for the present application.

Re Item V
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:
D1: US-B1-6 427 083
D2: WO 03/039664 A
D3: US-A-6 125 298

1.1 Claim 1 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved ("wherein ... the defibrillator has means for automatically connecting power to the defibrillator circuitry upon deployment of the electrodes"), which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result. The technical features necessary for achieving the result are specified in claims 2 and 3, respectively.

1.2 It is noted that disregarding the definition of the result to be achieved in claim 1, the remaining features of claim 1 do not require the exercise of an inventive step in the sense of Article 33(3) PCT. The reasons are as follows:

The document D1, which may be regarded as being the closest prior art to the subject-matter of claim 1, discloses a portable defibrillator (10) comprising a housing containing defibrillator circuitry and a disposable electrode assembly (4) external to said housing, the electrode assembly comprising two defibrillator electrodes (31a-31g, cf. col. 17 l. 27-32 and l. 65-67), at least one battery (184) for powering the defibrillator circuitry, and a connector (20, 21; cf. col. 16 l. 16-29) for connecting the

electrode and battery to the defibrillator housing, wherein the connector has power output terminals for connecting the at least one battery to the defibrillator circuitry and at least one high voltage input terminal or receiving a defibrillation voltage to be applied to the electrodes (cf. col. 16 l. 19-22 and l. 39-40, and fig. 17).

A stowage location for the electrodes on the defibrillator housing as defined in claim 1 is not explicitly disclosed in D1. Including such a stowage location on the defibrillator housing however is a matter of normal design procedure, which does not require the exercise of an inventive step, especially as almost any outer surface of the defibrillator housing may be regarded as a possible stowage location for the electrodes.

1.3 It is furthermore noted that if the technical features necessary for achieving the result defined in present claim 1 (i.e. additional features of claim 2 or 3) had been included in present claim 1, claim 1 would have met the requirements of the PCT with respect to novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT), the reasons being as follows:

The document D1, which is regarded as the closest prior art, discloses a defibrillator comprising the features as indicated under point 1.2 above. The problem to be solved may be regarded as to automatically connect power to the defibrillator circuitry when the electrodes are deployed (cf. point 1.1 above and p. 2 l. 1-3 of the present application). The alternative solutions proposed in claims 2 and 3, respectively, reside in the provision of a frangible electrical connection of the defibrillation electrodes (claim 2), or the provision of an insulating member interrupting a power supply circuit in the defibrillator (claim 3). Breaking of the frangible connection is detected and leads to a power supply circuit in the defibrillator being completed. Similarly, removal of the insulating member completes the power supply circuit. Thus the defibrillator may be automatically powered and turned on when the electrodes are deployed.

The document D3 discloses a defibrillator, wherein opening of a lid to access an electrode set activates a power generation circuit and turns the defibrillator on. The lid switch is a magnetic reed relay switch or a Hall effect sensor. No hint is given in

D3 to modify the means for turning on the power supply circuit in a manner as proposed in claims 2 or 3 of the present application, nor to apply such means to the defibrillator known from D1.

2. Dependent claims 4-6, if they had been made dependent on an independent claim including the features of present claim 2, would also have met the requirements of the PCT with respect to novelty and inventive step.

Re Item VI

Certain documents cited

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
D2 (WO 03/039664 A)*)	15.05.2003	17.10.2002	05.11.2001

*) It is noted that the document D2 is not relevant to novelty of the present claims, and does not constitute prior art in the sense of Rule 64.1 b) PCT since the priority of the present application appears to be validly claimed, cf. item II above.

Claims

1. A disposable electrode assembly for a portable defibrillator, the assembly comprising at least one defibrillator electrode, at least one battery for powering the defibrillator, and a connector for connecting the electrode and battery to the defibrillator, the connector having power output terminals for connecting the at least one battery to the defibrillator and at least one high voltage input terminal for applying a defibrillation voltage to the at least one electrode.

2. An assembly as claimed in claim 1, wherein the assembly comprises two defibrillation electrodes.

3. An assembly as claimed in claim 2, wherein the defibrillation electrodes are electrically connected externally of the defibrillator by a frangible connection which is broken when the electrodes are deployed for use.

4. An assembly as claimed in claim 1 or 2, wherein the at least one defibrillation electrode is sealed in a pouch and further including means for completing a power supply circuit to the power input terminals upon opening the pouch.

5. An assembly as claimed in any preceding claim, wherein the battery is housed in the connector.

6. An assembly as claimed in any of claims 1 to 4, wherein the battery is mounted on the rear of the at least one defibrillation electrode.

7. A combination of a defibrillator and an assembly as claimed in any one of claims 1 to 6.

8. A combination as claimed in claim 7 when dependent on claim 1 or 2, wherein the at least one defibrillation electrode has a stowage location on the defibrillator housing and removal of the electrode from the stowage location automatically connects power to the defibrillator.

9. A combination as claimed in claim 7 when dependent on claim 1, wherein the assembly comprises one defibrillator electrode and a second defibrillator electrode is attached to the exterior of the defibrillator housing.

10. A combination as claimed in claim 7 when dependent on claim 23, wherein the defibrillator has circuitry to determine when the frangible link is broken and upon such determination to complete a power supply circuit in the defibrillator.

11. A combination as claimed in claim 7 when dependent on claim 2 or as claimed in claim 10, wherein the assembly comprises a common housing for the defibrillation electrodes and the at least one battery, the common electrode/battery housing being removably fitted to the defibrillator housing and having power output and high voltage input terminals for connection

to corresponding terminals on the defibrillator housing.

12. A combination as claimed in claim 11, wherein the common housing is slidable into a complementary recess in the defibrillator housing, the sliding movement bringing the terminals on the two housings into engagement.

13. A combination claimed in claim 12, wherein the common housing comprises a shallow upper tray-like recess for accommodating the defibrillator electrodes and a deeper battery-containing recess occupying part of the area of the tray-like recess whereby the common housing has a stepped lower surface, wherein the defibrillator housing has a stepped recess complementary to that of the lower surface of the common housing, wherein the common housing is slid into the recess in the defibrillator housing from an edge thereof in a direction substantially parallel to the plane of the tray-like recess, and wherein the engaging terminals are located on riser portions of the lower surface of the common housing and the complementary recess in the defibrillator housing.